

Data Evaluation Report on the effects of saflufenacil on nitrogen transformation

PMRA Submission Number: 2008-0430

MRID#: 474308-02

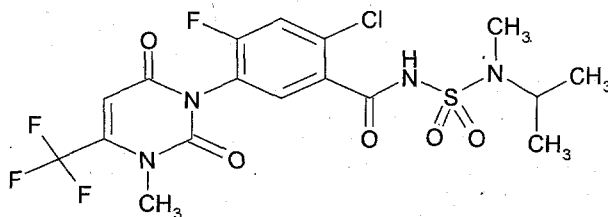
PMRA# for DER: 1604189

PMRA# for original study: 1599146

Data requirement EP
 PMRA Data Code: 9.9
 EPA DP Barcode: 349851
 OECD Data Point: IIIA 10.7.1
 EPA Guideline: n/a
 OPPTS Guideline: n/a

Test material: BAS 800 01 H **Guarantee:** 70.0% BAS 800 H

Active ingredient: saflufenacil
IUPAC: N'-[2-chloro-4-fluoro-5-(3-methyl-2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2H)-pyrimidinyl)benzoyl]-N-isopropyl-N-methylsulfamide
CAS name: 2-chloro-5[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2H)-pyrimidinyl]-4-fluoro-N-[(methyl(1-methylethyl)amino)sulfonyl]-benzamide
CAS No.: 372137-35-4
Synonyms: BAS 800 H
Structural formula:



Primary Reviewer: Janine Glaser (1009)
 Canada-HC-PMRA-EAD

Date: 2008-Aug-7

Secondary Reviewers: Anita Pease
 United States-EPA-OPP-EFED-ERB4

Date: 2009-Jun-09

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Date: 2008-Dec-17

PMRA Company Code BAZ
PMRA Active Code SFF

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PMRA Use Site Category 13, 14
EPA PC Code 118203

CITATION: Schulz L. 2008. Effects of BAS 800 01 H on the activity of soil microflora (nitrogen transformation test). 2008-Apr-24. BASF-2008/1010676; MRID-474308-02; PMRA-1599146.

EXECUTIVE SUMMARY

In a soil microbial activity study, the effects of the formulated product BAS 800 01 H on nitrogen transformation were investigated in a loamy sand soil. BAS 800 01 H was applied to samples of the soil at nominal test concentrations of 0.93 and 9.33 mg product/kg dry soil (0.65 and 6.53 mg a.i./kg dry soil), equivalent to 0.70 and 7.0 kg product/ha (0.49 and 4.9 kg a.i./ha) for a 5-cm soil depth, or 2.1 and 21.0 kg product/ha (0.15 and 14.7 kg a.i./ha) for a 15-cm soil depth. BAS 800 01 H treated soils and controls were incubated at approx. 20°C in the dark. Triplicate samples of each treatment were removed for analysis of mineral nitrogen 0, 7, 14, and 28 days after application. Deviations from control were 0.9-2.5% inhibition in the 0.93 mg product/kg dry soil treatment and 5.1-8.2% stimulation in the 9.33 mg product/kg dry soil treatment. Therefore, there were no significant effects (i.e., deviation from control was <25%) on nitrogen transformation at any application rate at any time period up to 28 days of incubation.

This study is classified as **FULLY RELIABLE** to PMRA and APVMA and **SUPPLEMENTAL** to EPA (data are not required for registration in the USA). The study appears to have been well conducted and reported. The results are suitable for use in regulatory risk assessment.

Results Synopsis

Process:	nitrogen transformation
Test duration:	28 days
Endpoint:	NO ₃ -N production
Soil concentration:	0.93 and 9.33 mg product/kg dry soil (0.65 and 6.53 mg a.i./kg dry soil)
Deviation from control:	0.9-2.5% inhibition and 5.1-8.2% stimulation

I. MATERIALS AND METHODS

Guideline: OECD 216
GLP: yes (certified laboratory)
Testing facility: BioChem agrar, Labor Für biologische und chemische Analytik GmbH, Gerichshain, Germany
Dates of work: 2008-Mar-19 to 2008-Apr-24
Deviations: none

A. Test substance

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Name: BAS 800 01 H
Type of formulation: WG (water dispersible granules) formulation
Batch No.: 1641-87
Expiry date: 2009 Sep 12
Content: 68.8% saflufenacil (analysed)

Table 1: Physical and chemical properties of active substance

Parameter	Value
Water solubility	pH 4 0.0014 g/100 mL
	pH 5 0.0025 g/100 mL
	pH 7 0.21 g/100 mL
	pH 9 not determined due to degradation
Vapour pressure	4.5×10^{-15} Pa at 20°C
	2.0×10^{-14} Pa at 25°C
UV absorption	pH 1.12 6.94
	λ_{\max} (nm) 271.8 271.4
	ϵ (L/mol-cm) 9539 9708
pK _a	4.41
log K _{ow}	2.6

B. Test solutions

Test item mixed with: deionised water
Method of preparation: 200 g sieved soil (2 mm) was treated with 7.20 mL stock solutions (deionized water)

C. Test soil

Soil nomenclature : loamy sand
Collection depth : 20 cm
Batch no.: 1/2008
Source: Schlag 34/2, Wassergut Canitz, Saxony, Germany
Date of collection: 2008 Feb 8
Storage temperature: approx. 4°C
Storage duration: <2 months

Particle size distribution (% w/w):
Sand (2-0.063 mm): 50.6
Silt (0.063-0.002 mm): 39.5
Clay (<0.002 mm): 9.8

Soil properties:
% organic carbon: 1.43
biomass (mg microbial C/100 g dry soil): 30.56

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% microbial C of organic carbon:	2.14
% nitrogen:	0.13
pH:	6.7
Cation exchange capacity (cmol ⁺ /kg soil):	9.5

History of soil:

Pest control products not used since:	1990
Fertilisers not used since:	2003
Crops:	fallow ground

D. Design of biological test

Each 200 g dry soil sample was amended with 1.0 g Lucerne-grass-green meal (consisting of 43.0% carbon and 2.82% nitrogen). One additional soil sample (without Lucerne meal) was used for determination of the initial nitrogen content (1.12 mg NO₃-N/100 g dry soil). Rates of 0.93 and 9.33 mg product/kg dry soil (0.65 and 6.53 mg a.i./kg dry soil, respectively) were applied on the soil, corresponding to 0.70 and 7.0 kg product/ha (0.49 and 4.9 kg a.i./ha) for a 5-cm soil depth, or 2.1 and 21.0 kg product/ha (0.15 and 14.7 kg a.i./ha) for a 15-cm soil depth. In addition, an untreated soil control was tested. Each flask (500 mL wide-mouth glass flasks) served as one replicate filled with 200 g dry soil. The test was conducted with 3 replicates per treatment level. The test was conducted at 19.7-21.0°C in the dark.

D. Observation and measurements

At day 0 (3 hours), and after 7, 14, and 28 days of incubation, subsamples (moist samples equivalent to 10 g dry soil) were taken from each flask. The content of ammonium (NH₄-N), nitrite (NO₂-N) and nitrate (NO₃-N) was measured with a Bran + Luebbe Autoanalyzer II. The water content of the soil in each test vessel was determined at test start (after application) and adjusted once a week to the required range of 40-50% of WHC. The pH values were measured at test start (after application) and on day 28.

II. RESULTS

A. Physical and chemical parameters

The soil pH was 6.5 (at all treatment levels at days 0 and 28). The water content was 15.71-16.49 g/100 g dry soil (equivalent to 41.49-43.56% of water holding capacity).

B. Biological findings

The deviation from the control did not exceed 25% after 28 days (Table 2).

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Table 2: Effects of BAS 800 01 H on nitrogen turnover in loamy sand soil given as deviation from control

	Control	0.93 mg product/kg dry soil (0.65 mg a.i./kg dry soil)		9.33 mg product/kg dry soil (6.53 mg a.i./kg dry soil)	
Day	mg NO ₃ -N/ kg dry soil/day	mg NO ₃ -N/ kg dry soil/day	% deviation from control	mg NO ₃ -N/ kg dry soil/day	% deviation from control
0-7	4.3	4.2	-2.5	4.5	+5.1
7-14	2.5	2.5	-1.2	2.7	+8.2
14-28	1.6	1.6	-0.9	1.7	+6.9

- = inhibition; + = stimulation

C. Validity criteria

The coefficients of variation in the control (NO₃-N) were maximum 6.9% and thus fulfilled the demanded range (≤15%) (Table 3).

Table 3: Variation in control replicates on NO₃-N in loamy sand soil given as % coefficient of variation

	Day 0	Day 7	Day 14	Day 28
% c.v.	3.1	3.0	6.9	3.8

D. Test with toxic reference substance

The reference item was dinoterb (purity 98.0 ± 0.5%). The reference item was tested in a separate study (2008 Jan 29 to Feb 26). Dinoterb caused effects of +27.7%, -60.8% and +68.1% (required ≥25%) on the nitrogen transformation at the tested concentrations of 6.80, 16.00, and 27.00 mg/kg dry soil, respectively, 28 days after application. Thus, the test with toxic reference substance demonstrates the sensitivity of the test system.

III. STUDY DEFICIENCIES

None.

V. CONCLUSIONS

This study is classified as **FULLY RELIABLE** to PMRA and APVMA and **SUPPLEMENTAL** to EPA (data are not required for registration in the USA). The study appears to have been well conducted and reported. The results are suitable for use in regulatory risk assessment. BAS 800 01 H has negligible effects on nitrogen turnover of soil microflora up to 9.33 mg product/kg dry soil (6.53 mg a.i./kg dry soil), which corresponds to 7.0 kg product/ha (4.9 kg a.i./ha) for a 5-cm soil depth, or 21.0 kg product/ha (14.7 kg a.i./ha) for a 15-cm soil depth.